

### **REMARKS**

This Amendment is responsive to the final Office Action of October 17, 2003 and the Advisory Action of March 23, 2004. Applicant would initially like to thank the Examiner for the informal telephone conference of March 19, 2004. Claims 1, 7-9, 15, 16, 25-29 and 32 have been amended. Claims 23 and 24 have been canceled without prejudice. Thus, Claims 1-22 and 25-34 are pending in this case. Reexamination and reconsideration are respectfully requested.

### **GENERALLY**

During the March 19, 2004 telephone conference between the Examiner and Applicant's counsel, Vic Lin, the Examiner suggested that the Applicant amend the claims to clarify the separateness of the contact urinalysis pad and the reagent-free absorbent strip by further stating that the urinalysis pad is composed of a first material and that the absorbent strip is composed of a second material. As shown in the above Listing of Claims, Applicant has herein revised the claims according to the Examiner's suggestions.

The Examiner also recommended that Applicant file a Rule 132 declaration regarding the unexpected benefits discussed during the phone conference. Accordingly, Applicant has enclosed a Rule 132 Declaration of Raphael Wong discussing the unexpected results.

### **CLAIM REJECTIONS – CLAIMS 24 & 30 – § 112**

In the final Office Action, Claims 24 and 30 were rejected under 35 U.S.C. § 112, second paragraph, as being indefinite. Based on the telephonic interview of February 6, 2004, Applicant's counsel clarified that the recited "lateral flow immunoassay strip" was a separate strip as shown in a preferred embodiment illustrated in Figures 8 and 9. It was agreed to by Examiner Alexander and Applicant's counsel that no further amendments were necessary to resolve the § 112 concerns.

### **CLAIM REJECTIONS – CLAIMS 1-34 – §§ 102(b) and 103**

In the final Office Action, Claims 1-34 were rejected under as being either anticipated by Horstman et al. (US 5,006,474) or unpatentable over Horstman et al. in view of Lappe (US 5,916,815). Pursuant to the agreement on the claims reached between Examiner Alexander and Applicant's counsel during the telephonic interview of February 6, 2004, Applicant has amended the claims accordingly.

In particular, all independent claims, including the method claims, have been amended to recite that the non-immunoassay contact urinalysis, or detection, pad is configured to detect adulterants. Applicant has amended particular dependent claims to specify certain adulterants being detected.

As suggested by the Examiner, Applicant has amended independent Claim 16 to include both a lateral flow immunoassay strip as well as a non-immunoassay contact detection pad adapted to detected one or more specific adulterants.

As agreed to in the telephonic interview which is memorialized in the Interview Summary enclosed herewith, Horstman et al. do not teach or suggest the use of a

separate absorbent strip to wick urine to a contact detection, or urinalysis, pad that is adapted for detecting one or more adulterants. It was further agreed that this feature is not taught or suggested in any of the prior art currently of record.

All of the independent claims have been amended to recite this feature. Applicant further submits that the dependent claims recite additional features not found in Horstman et al.

Therefore, Applicant respectfully submits that each independent claim is allowable over all prior art currently of record, including Horstman et al. and Lappe. Applicant further submits that the dependent claims are allowable over the cited reference for their dependence on allowable independent claims, for the further patentable features recited therein, and for any further grounds as may be recognized by the Examiner.

#### **ADVISORY ACTION**

The Advisory Action states that the following references may be relevant to the claims: US 2003/0039583 (the "'583 Published Application" or "Miller et al."), and U.S. Patent Nos. 6,689,618, 6,514,769 and 6,503,726 (collectively, the "Dip Stick Patents").

In regard to the '583 Published Application, particularly with respect to Figure 4 therein, the reference does not teach or suggest a non-immunoassay contact urinalysis pad is composed of a first material and separate from a reagent-free absorbent strip that is composed of a second material. As discussed in the March 9, 2004 telephone conference, Miller et al. teach that the reagent composition is disposed on the very same pad that also serves as the absorbent strip. This leads to the undesirable result

of the color(s) being forced to the distal end of each strip 306, 307 due to the wicking liquid action. Miller et al. do not teach a separate reagent-free absorbent strip.

The separateness of the reagent-free absorbent strip and the contact urinalysis pad is not obvious as evidenced in the enclosed Rule 132 Declaration of Raphael Wong. Applicant's claimed invention includes an adulterant or urinalysis pad that comprises the reagent composition, which pad is physically separate from the reagent-free absorbent strip.

Furthermore, Applicant has amended independent Claim 25 to recite, among other things, that the reagent-free absorbent strip overlaps at least a portion of the separate non-immunoassay contact detection pad.

With respect to the Dip Stick Patents, Applicant respectfully submits that none of these patents teaches or suggests the claimed structure as described above. In particular, the '726 Patent to Anne et al. is directed to a chromogenic substrate to detect urine adulteration. Anne et al. do not show a urinalysis pad having a reagent composition that is physically separate from the reagent-free absorbent strip.

Lee (US 6,514,769) teaches an absorbent strip that is in fluid communication with both an integrity determinant pad 300 and an analyte test strip 105A. Lee recognizes, therefore, that some fluid communication may occur between the integrity determinant pad 300 and the analyte test strip 105A, but tries to minimize this effect by saying that it is "not in appreciable fluid communication." (col. 6: 24-31). Applicant has amended the claims to recite that the reagent-free absorbent carrier does not have any fluid communication with an immunoassay. This is clearly disclosed in all of Applicant's preferred embodiments. The avoidance of any and all fluid communication with an

immunoassay test strip avoids the complications that may occur otherwise, whether the amount of communication is appreciable or not.

Lastly, Applicant is the President of Branan Medical Corporation which is the owner of U.S. Patent No. 6,689,618 to Chen. Being very familiar with Chen, Applicant can confidently state that the reference does not teach the structure as claimed herein, namely, a non-immunoassay contact urinalysis pad composed of a first material in fluid communication with a reagent-free absorbent strip composed of a second material.

Thus, Applicant respectfully submits that none of the Dip Stick Patents teach or suggest the claimed invention.

#### **SUMMARY**

Based on the above amendments and accompanying remarks, Applicant respectfully submits that all pending claims are in condition for allowance and respectfully requests a Notice of Allowance. Applicants encourage the Examiner to telephone the undersigned attorney if it appears that a telephone conference would facilitate allowance of the application.

I hereby certify that this correspondence is being deposited with the United States Postal Service as first class mail in an envelope addressed to: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450 on

April 19, 2004

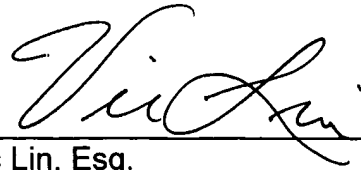
by Angela Williams



Signature

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